UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	No. 19-md-2875-RBK Hon. Robert Kugler

REPLY MEMORANDUM OF LAW IN SUPPORT OF THE MEDICAL MONITORING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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I. INTRODUCTION

Defendants' opposition to medical monitoring class certification reveals that there is a straightforward common dispute here: Plaintiffs advocate monitoring, and have proposed a specific class-wide monitoring program; Defendants want no monitoring at all.

The specific issues Defendants raise to show purported variation in law or fact are either irrelevant in context, already reflected in the proposed class structure, speculative with no support in the record, or simply are misstatements of law. Plaintiffs used a conservative approach to seek monitoring only for those exposed to vast, dangerous amounts of contaminants, having nothing to do with their individual behavior, histories, or families. The class device, under Rule 23(b)(2)—the preferred and logical approach, as shown by current case law—or under (b)(3), is efficient and equitable, viewed on its own, and as compared to the alternatives.

II. ARGUMENT

Plaintiffs seek certification of both an Independent Claim Class ("ICC") and a Remedy Class ("RC") ("Classes") under Rule 23(b)(2) and, in the alternative, argue that the ICC satisfies Rule 23(b)(3). Defendants effectively concede that Plaintiffs satisfy the Rule 23(a) and (g) elements of numerosity, commonality, typicality, and adequacy. Their challenges to predominance fail, and their arguments about cohesiveness, superiority, and the implied element of ascertainability largely duplicate the failed predominance arguments.[1] Here, because plaintiffs were exposed to the same carcinogens, from the same group of products, and suffered the same

[1] Under Rule 23(b)(2), the "the class claims must be cohesive." *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998). Cohesiveness means that the claims "will not require individual proof from each class member to establish a violation of the law." *Jane v. Rodriguez*, No. 20-5922, 2020 WL 6867169, at *11 (D.N.J. Nov. 23, 2020). Cohesiveness is similar to predominance, and superiority typically follows predominance. To the extent Defendants assert that Rule 23(b)(2) exists primarily for civil rights cases, that is patently untrue, as the body of case law certifying medical monitoring cases under (b)(2) reflects. *See* Ex. 6, Pl's Mot. to Certify Med. Monitoring Class ("Pl's Cert. Br.") at 21.

injuries, the Classes should be certified.

A. Common Issues of Law Predominate Over Individual Questions

The core defect in Defendants' argument about the existence and import of purported variations in state laws related to medical monitoring is that any variations are either immaterial or addressed in the class structure. Specifically, the Classes reflect that some states recognize an independent claim for medical monitoring, while others recognize medical monitoring as a remedy. *See* Pl's App. A.[2] Defendants' argument that nationwide medical monitoring classes cannot be certified is flatly wrong. *See In re Diet Drugs Prods. Liab. Litig.*, No. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999) (certifying nationwide medical monitoring class under Rule 23(b)(2)); *In re Telectronics Pacing Sys.*, 172 F.R.D. 271, 292 (S.D. Ohio 1997) ("[S]tate law does not need to be universal in order to justify nationwide class certification.").

Defendants largely overlook Plaintiffs' authority, instead citing inapposite cases with insufficient effort to address legal differences.[3] However, a plaintiff can show that variations among state laws do not defeat cohesion or predominance, "by identifying the relevant legal issues and categorizing the applicable law according to their differences, and convincing the court that those differences do not pose 'insuperable obstacles' to managing the class." *Sanders v. Johnson*

[2] Even that distinction tends to collapse in practice, because both groups require underlying wrongful conduct. However, that fact is not relevant because the EL Plaintiffs have separately alleged and have shown that common issues will prove warranty and fraud claims. *See* Opening Br. at 15. Where Defendants assert the existence of variations of law as to those claims, Plaintiffs refer to the EL Plaintiffs' reply brief.

[3] *See Almond v. Janssen Pharm., Inc.*, 337 F.R.D. 90, 99 (E.D. Pa. 2020) (arguing that Pennsylvania law should apply rather than conducting its own state by state analysis); *Sanders*, 2006 U.S. Dist. LEXIS 35881, at *12 (Plaintiff only analyzed state law variations in terms of injury requirements and did not conduct its own research); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 70 (S.D.N.Y. 2002) (Plaintiffs "assert that New York choice of law principles permit the application of the substantive law of New Jersey to the claims of all class members, regardless of whether they are New Jersey domiciliaries"); *In re NHL Players' Concussion Injury Litig.*, 327 F.R.D. 245, 263 (D. Minn. 2018) ("Plaintiffs maintain, however, that Minnesota law on medical monitoring can still be applied on a classwide basis.").

& Johnson, Inc., No. 03-2663 (GEB), 2006 WL 1541033, at *4 (D.N.J. June 2, 2006). Defendants' cases are inapposite for other reasons as well. *See, e.g., Grovatt v. St. Jude Med. Inc. (In re St. Jude Med., Inc.)*, 425 F.3d 1116, 1122 (8th Cir. 2005) (holding that monitoring would be duplicative for class of mechanical heart valve recipients).

Here, in any case, the parties agree that the laws of numerous states align with the proposed Classes. With respect to the proposed ICC, Defendants concede that Florida, Massachusetts, Pennsylvania, Utah, and West Virginia recognize medical monitoring as an independent cause of action and do not require a showing of injury (or require only subcellular injury, which Plaintiffs have pled). Ex. 1, Def's Med. Monitoring Opp'n ("Opp'n") (Dkt. No. 2012), App. A at 8, 14, 25, 27, 29.

Likewise, with respect to the proposed RC, Defendants recognize that California, Maryland, and Ohio permit medical monitoring as a remedy and have no requirement of present injury. *Id.* at 32, 41, 44, 46; *see also Hardwick v. 3M Co.*, No. 2:18-cv-1185, 2022 WL 668339, at *25-27 (S.D. Ohio Mar. 7, 2022) (certifying a medical monitoring (b)(2) class exposed to a toxic chemical contaminant PFAS over defendant's argument that individual risk factors varied; determining the contours of the monitoring program would be decided by a science committee). *Hardwick* set its class definition based on each members' degree of exposure, as here. *Id.* at *18.[4] Overall, the very question of whether certain states' laws would permit medical monitoring as a claim or remedy is itself a common question that would be resolved at once for all class members after class certification.

[4] The Middlesex County Superior Court in New Jersey also recently certified a medical monitoring class for individuals exposed to PFAS under New Jersey Rule of Civil Procedure 4:32-1(b)(2). *See Tomas Vera et al. v. Middlesex Water Co*, No. MID-L-6306-2, 2022 N.J. Super. Unpub. LEXIS 774, at *22 (N.J. Super. Ct., Apr. 21, 2022) (noting members of the class "primarily [sought] injunctive relief and medical monitoring, as well as other monetary damages").

B. Defendants' State-Law Analysis is Replete with Errors and Premised on an Incorrect Understanding of the Governing Analysis

Defendants assert that the proposed twenty-eight-state ICC wrongly includes twenty-three states that lack controlling decisional law establishing that Plaintiffs can bring independent claims for medical monitoring in these states. Ex. 1, Opp'n at 7; Ex. 1, Opp'n, App. A at 3-28. However, the absence of clear and controlling caselaw is not sufficient grounds to reach that conclusion. When a state's highest court has not ruled on an issue, the Court is "charged with predicting how that court would resolve the issue." *Ill. Nat'l Ins. Co. v. Wyndham Worldwide Operations, Inc.*, 653 F.3d 225, 231 (3d Cir. 2011); *see also McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 662 (3d Cir. 1980) ("[I]t is a task which we may not decline."). Courts "must take into consideration: (1) what that court has said in related areas; (2) the decisional law of the state intermediate courts; (3) federal cases interpreting state law; and (4) decisions from other jurisdictions that have discussed the issue." *Ill. Nat'l Ins. Co.*, 653 F.3d at 231.

Defendants ignore persuasive decisions indicating that the highest courts of the challenged states would permit an independent medical monitoring claim.[5] *See, e.g., Cook v. Rockwell Int'l Corp.*, 778 F. Supp. 512, 514 (D. Colo. 1991) ("the Colorado Supreme Court would probably recognize, in an appropriate case, a tort claim for medical monitoring."); *Bell v. 3M Company*, 344 F. Supp. 3d 1207, 1224 (D. Colo. 2018) (same); *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 819 (D.C. Cir. 1984) (predicting that the District of Columbia Court of Appeals would recognize a "cause of action for diagnostic examinations in the absence of proof of actual injury"). The same is true of Arizona, Montana, New Hampshire, and Vermont:

[5] Or, in the case of New York, Defendants ignore relevant authority interpreting a state high court decision. *See Burdick v. Tonoga, Inc.*, 60 Misc. 3d 1212(A) at *8-9 (N.Y. Sup. Ct. 2018), *aff'd*, 179 A.D.3d 53 (2019) (holding that the injury requirement is satisfied by exposure to a harmful substance and presence of the substance in the plaintiffs' bodies or some indication of disease induced by the substance).

persuasive caselaw indicates that each state would recognize an independent medical monitoring claim. Pl's App. A. at 3, 16, 18, and 26. Similarly, Delaware, Oregon, and Rhode Island appear to permit independent medical monitoring claims where a plaintiff adequately pleads injury. *Id.* at 5, 2, and 24.

Seven states are silent as to whether a plaintiff may bring an independent medical monitoring claim.[6] Defendants incorrectly conclude that the absence of relevant caselaw is dispositive of the issue in their favor. The absence of state decisional law on a particular issue does not prevent this Court from reaching a conclusion about the likely outcome of that issue if it were to come before the highest court in a state. *See Berrier v. Simplicity Mfg.*, 563 F.3d 38, 46 (3d Cir. 2009) (recognizing bystander's right to recover under products liability law even though the Pennsylvania Supreme Court had not yet recognized that right, noting that "it has not expressly rejected such a claim either").

Defendants do not dispute that fourteen of the states and territories in the RC permit medical monitoring as a remedy.[7] With respect to five states—Connecticut, Georgia, Indiana, Nebraska, and Tennessee—Defendants assert that the relevant law is so unclear that this Court should exclude these states from the RC. Ex. 1, Opp'n at 10-11. Yet, the Sixth Circuit has stated that "two Tennessee cases at least suggest that the state recognizes medical monitoring claims." *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 n.7 (6th Cir. 2005) (citing *Laxton v. Orkin Exterminating Co., Inc.*, 639 S.W.2d 431 (Tenn. 1982) and *Newsom v. Markus*, 588 S.W.2d 883, 887 (Tenn. Ct. App. 1979)). At least one Connecticut district court has held that a plaintiff could pursue medical monitoring as a remedy under Connecticut law. *Martin v. Shell Oil Co.*, 180 F.

[6] Alaska, Idaho, Maine, New Mexico, North Dakota, South Dakota, and Wyoming. Pl's App. A at 1, 8, 11, 18, 20, 24, and 26.

[7] Those states are Arkansas, Guam, Kansas, N. Mariana Islands, Oklahoma, Puerto Rico, South Carolina, Texas, Virgin Islands, Virginia, and Washington.

Supp. 2d 313, 323 (D. Conn. 2002). And the Indiana Court of Appeals also held that a plaintiff was entitled to medical monitoring as a remedy for a claim of nuisance. *See Allgood v. GMC*, No. 1:02-cv-1077-DFH-TAB, 2005 WL 2218371, at *4-5 (S.D. Ind. Sep. 12, 2005).

Overall, Defendants have not identified a single state that actually bars medical monitoring as a remedy.[8] No surprise: "the use of a court-supervised fund to administer medical-surveillance payments . . . is a highly appropriate exercise of the Court's equitable powers." *See Ayers v. Jackson*, 106 N.J. 557, 608 (1987).[9]

C. The Other Purported Differences Are Overstated or Irrelevant

Defendants also assert that there are material variations in injury requirements and treatment and detection issues that preclude class certification. Not so. First, and dispositive on the question of injury, this Court has already held that exposure to contaminated products constitutes an injury-in-fact. MTD Op. No. 2, Dkt. No. 728 at 15. Further, Plaintiffs have alleged that all members of the proposed Classes have suffered cellular damage and/or genetic harm by their exposure to NDMA and/or NDEA through their consumption of contaminated VCDs such that they have suffered cellular injury. Ex. 2, Med. Monitoring Compl. (Dkt. No. 1709) at 117; *see also* Ex. 3, Panigrahy Decl. at 164. Plaintiffs do not allege a mere increased risk of harm, but instead allege present injuries in the form of cellular damage and/or genetic harm that materially increases their risk of contracting specific cancers. *See* Ex. 4, Madigan Rpt. at 8-10. As such, all members of the proposed Classes have suffered a present physical injury that meets or exceeds the

[8] Additionally, this Court has previously recognized that the following states may allow a plaintiff to recover damages for medical monitoring as a remedy for another tort: Alabama, Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Michigan, Mississippi, Nebraska, New Jersey, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wisconsin. *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. 2875 (RBK/KW), 2021 WL 364663, at *89-90 (D.N.J. Feb. 3, 2021).

purported requirements asserted by Defendants. *See* Ex. 1, Opp'n at 9, App. A; *see also* Pl's App.[10]

To the extent that these injuries are insufficient to satisfy the element of injury, this would constitute a *common* failure of proof across the class, which "is properly addressed at trial or in a ruling on a summary-judgment motion. The allegation should not be resolved in deciding whether to certify a proposed class." *Amgen, Inc. v. Conn. Ret. Plans and Trust Funds*, 133 S. Ct. 1184, 1197 (2013). As laid out in Appendix A, the Court may exercise its power to: (1) divide the ICC into two classes, (a) one encompassing all states that permit medical monitoring as an independent claim and do not require present physical injury or require only a showing of subcellular injury, and (b) the other encompassing all other states that permit medical monitoring as an independent claim; and/or (2) divide the RC into two classes, (a) one encompassing all states that do not permit medical monitoring as an independent claim and do not require present physical injury or require only a showing of subcellular injury, and (b) the second encompassing all other states that do not permit medical monitoring as an independent claim. *See, e.g.*, *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 287 (S.D. Ohio 1997) (dividing a single medical monitoring class into two subclasses based on whether state requires present physical injury to recover for medical

[10] Defendants' proposed "toxic tort" grouping of states that limit medical monitoring relief to toxic tort cases—New Jersey and Missouri—is a fiction. In Missouri, a medical monitoring remedy is conditioned on exposure to toxic *substance*s. *Meyer v. Fluor Corp.*, 220 S.W.3d 712, 717 (Mo. 2007) (discussing medical monitoring as an appropriate remedy when a plaintiff is exposed to "toxic substances" due to the latent nature of the injury). The members of the proposed classes were exposed to toxic substances and as such fall squarely within the parameters articulated by the Missouri Supreme Court. *See id.* at 718 ("A physical injury requirement is inconsistent with the reality of latent injury and with the fact that the purpose of medical monitoring is to facilitate the early diagnosis and treatment of latent injuries caused by exposure to toxins."); *cf. Ratliff v. Mentor Corp.*, 569 F. Supp. 2d 926, 929 (W.D. Mo. 2008) ("[T]his Court [believes] that the Missouri Supreme Court would dismiss medical monitoring claims that do not result from exposure to toxic substances"). The New Jersey Supreme Court has held that whether an injury arises from a toxic tort "in itself is not a distinguishing metric." *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 71 (2008).

monitoring). Each of these classes would be subject to uniform standards of proof and the relief accruing to each class would uniformly benefit the entire class. What is important is that the relief sought by the named plaintiffs should benefit the entire class." *Neal v. Casey*, 43 F.3d 48, 59 (3d Cir. 1994).

Finally, Defendants' arguments about treatment and detection procedures miss the mark entirely: it is either undisputed, or a common question, whether the cancers caused by NDMA and NDEA can be detected, and that early detection affects treatment and outcomes. [redacted]

D. Common Issues of Fact Predominate Over Individual Questions

1. Causation and Exposure

Defendants argue that the causation inquiry is individualized even though all class members were exposed to the carcinogens in the same way, by ingesting the contaminated pills. Moreover, medical monitoring law does not require a unique injury (meaning, an injury or illness whose provenance can only be the defendants' conduct, versus broad categories such as bacteria, cancer, toxins, etc.); if that were the case, there would never be medical monitoring. Plaintiffs have already established "exposure greater than normal background levels" and that "as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease." *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 265 (3d Cir. 2011) (quotations omitted).

Plaintiffs' have set a conservative, high level of cumulative exposure to NDMA or NDEA exposure due to Defendants' conduct that would create a significantly increased risk of contracting specified cancers in *any* individual, thus blunting Defendants' argument. *See* Madigan Rpt. at 8-10; Panigrahy 90-91, 102, 175, 194-95. Simply put, the levels of exposure outside of the contaminants is dwarfed compared to the massive contamination, especially given Plaintiffs'

conservative approach by setting such high thresholds. Further, here, unlike in other cases, this matter has been phased such that Plaintiffs' general causation experts have already survived *Daubert*. *See* Daubert Order 1 (Dkt. No. 1958); Daubert Order 2 (Dkt. No. 1974).

Defendants primarily rely on an inapposite case, *Gates*, that involved environmental exposure to a carcinogen found in wastewater that seeped into nearby residents' drinking water. *Gates*, 655 F.3d at 259. The exposure was environmental rather than a due to a drug, implicating facts such as the period of time that a class member may have resided in the town, whether and how much wind affected any exposure, the amount of wastewater that was dumped during that particular time period, and other. *Id.* at 265-267 (exposure could vary "drastically" not only year-to-year but even hour-to-hour). Here, by contrast, each class member's individual exposure to NDMA or NDEA can be ascertained by examining the class member's NDC prescription records. Ex. 6, Pl's Cert. Br. at 9 (citing Ex. 7, Decl. of Laura R. Craft (Dkt. No. 1748-2) ("Craft Decl.")).

This case is on all fours with *In re Diet Drugs*, 1999 WL 673066, at *13, where the court certified medical monitoring classes under Rule 23(b)(2) based on the duration and amount of the drug each class member took. *Accord Baker v. Sorin Grp. Deutschland GMH*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *30 (M.D. Pa. Oct. 23, 2017) ("necessity of proving one threshold fact for each class member is certainly not significant or predominant in light of all of the other factual and legal issues common to the class"). Regardless of a class member's degree of prior exposure to NDMA or NDEA, the effect of continuing exposure to these carcinogens is *cumulative*, meaning that the risk of developing cancer grows as the concentration and duration of exposure to contaminated Valsartan increases. *See* Ex. 3, Panigrahy Rpt. at 12 ("the carcinogenic effect is based on both dose and duration of exposure"). Defendants' references to certain Plaintiffs' tobacco use or other possible exposures are likewise irrelevant to the causation inquiry.

Defendants' contaminated Valsartan caused "a significantly increased risk of contracting" cancer in Plaintiffs by contributing to their cumulative exposure to the carcinogens, thereby necessitating medical monitoring. *Gates*, 655 F.3d at 265.

2. Medical Necessity

"Medical necessity" means the monitoring program is "different from that normally recommended in the absence of exposure." *Barnes*, 161 F.3d at 146. To argue this element is not satisfied, Defendants quote *Barnes* out of context to assert that Plaintiffs must present evidence about their individual medical histories (a requirement that could preclude any monitoring case). *However, the complete quotation from Barnes is a case-specific conclusion regarding whether medical monitoring was warranted due to plaintiff's smoking of cigarettes:* "Although the general public's monitoring program can be proved on a class wide basis, an individual's monitoring program by definition cannot. In order to prove the program he requires, a plaintiff must present evidence about his ***individual smoking history*** and subject himself to cross-examination by the defendant about that history." *Id.* (emphasis added). [redacted] This situation is more factually similar to *In re Diet Drugs*, where "[t]he dates, duration and amounts of ingestion and the combination of drugs ingested can be confirmed through the use of fact sheets and medical records." *In re Diet Drugs*, 1999 WL 673066, at *13.

[redacted]

[11] Defendants' citation to *Arch* is similarly distinguishable because it was also a tobacco case, so it bore similar factual complications due to the self-administration of cigarettes. *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 489 (E.D. Pa. 1997).

[redacted]

More importantly, this overlooks the essential point that persons in the class that Dr. Kaplan would prescribe medical monitoring to are not a part of a *general population*, but rather people exposed to specific excessive amounts of NMDA or NDEA, such that *general screening guidelines* would be insufficient. Ex. 9, Teitelbaum Rpt. at 18-24. The proposed medical monitoring program is supplementary to the guidelines applicable to the general population because exposure to NDMA or NDEA as a result of Defendants conduct has placed class members at increased risk to developing cancer as compared to the general population. The guidelines for this specific class of exposed persons will therefore necessarily be "different than the one that would have been prescribed in the absence of that particular exposure and increased risk." Ex. 10, Kaplan Rpt. at 3-4, 6. [redacted]

Defendants' assertion that U.S. Preventive Services Task Force only recommends enhanced cancer screening on the basis of exposure to a carcinogen for heavy smokers between the ages of 55 and 80 is likewise a red herring. Ex. 1, Opp'n at 18. It is because of exposure to NDMA and NDEA through Valsartan that the screening in Plaintiffs' medical monitoring proposal goes beyond general guidelines. [redacted]

[redacted]

Ex. 10, Kaplan Rpt. at 4.

Defendants' argument that the monitoring program fails to factor in harms as a result of screening is false: for example the Galleri test is a simple blood prick, certain extra care in a physical should be a non-issue. In any event, this speaks only to the commonality of the program: Defendants believe any program is inherently too risky. Yet, Courts are able to oversee the development of programs all the time. *See, e.g.*, *Hardwick*, 2022 WL 668339, at *26 (collecting authority for the proposition that courts have established science panels in medical monitoring cases).

Further, there is no requirement to show that monitoring carries *no risk* – the only question is whether benefits outweigh risks. [redacted]

[redacted]

[redacted]

Finally, Defendants argue that any class claims against Aurobindo and Mylan for pancreatic cancer cannot be certified because of their common defense that there is no way to screen for pancreatic cancer. Ex. 1, Opp'n at 19. First, Dr. Lagana and Dr. Hecht have not been limited on NDEA, and Plaintiffs will be seeking clarification to establish that Dr. Panigrahy is not limited in his NDEA opinions, as the Court ruled on the record during the Daubert hearing. Daubert Order 1 at 3. In addition, Dr. Kaplan identified Galleri, a multi-cancer early detection (MCED) test, as an existing simple blood test that could detect pancreatic cancer. Ex. 10, Kaplan Rpt. at 5. [redacted]

3. Variation in Costs Do Not Predominate

Defendants argue that the variability of services and costs in the proposed medical monitoring class weighs against class certification. Defendants miss the mark. First, the sole case cited by Defendants in this section concerns only 23(b)(3) class certification and is also legally

and factually distinguishable because it was notable for its treatment of future plaintiffs, an issue not implicated here.[13] Even as to (b)(3), Defendants greatly overstate the variability of services and costs, as well as the accompanying uncertainty. For example, Dr. Chan cites an empirical study that identifies the percentages of patients who decline colonoscopies, which demonstrates that data-driven studies of patient behavior exist which can be used to understand, and predict, non-participation rates among the Class Members. *See* Ex. 11, Chan Rep. ¶ 72. Meanwhile, Dr. Song explains that a common data-based methodology for estimating spending on medical monitoring exists. Ex. 12, Song Rpt. ¶ 32-42. Though Defendants may prefer alternative methodologies to those discussed by Dr. Song, this is ultimately a factual disagreement for the ultimate finder of fact rather than a justification for denying class certification.

4. Purported Variation in Dosing Does Not Predominate

Finally, Defendants cite to *Rowe*[14] to argue that variation in exposure exists. Ex. 1, Opp'n at 15 (first quoting *Rowe v. E.I. duPont de Nemours & Co.*, No. CIV. 06-1810 (RMB), 2008 WL 5412912, at *17 (D.N.J. Dec. 23, 2008)). Yet Plaintiffs have specifically accounted for variables including dose, duration, and manufacturer in their class definition, so this challenge totally lacks merit. *See* Ex. 2, Med. Monitoring Compl. at 182-83; Ex. 6, Pl's Cert. Br. at 6-10.

Defendants' only remaining critique with intra-manufacturer variation in contamination between batches is misplaced, because this variation is practically insignificant at the levels contamination that were observed by the FDA.[15] Ex. 1, Opp'n at 15. API produced by Hetero

[13] *Georgine v. Amchem Prods.*, 83 F.3d 610, 620, 632 (3d Cir. 1996) (unlike here, the class was "a hodgepodge of factually as well as legally different plaintiffs" of "all present and future claims of class members for asbestos-related personal injury").

[14] Like many of the other cases Defendants cite, *Rowe* is an environmental exposure case, a more abstract form of exposure than ingestion of a prescription drug,

[15] *See* Ex. 13, U.S. Food & Drug Admin., Laboratory Analysis of Valsartan Products (May 2,

contained between three and four times of the FDA's Acceptable Daily Intake (ADI) for NDMA. Ex. 13, FDA Analysis. Likewise, ZHP's API contained between 137 times and 210 times the acceptable levels.[16] *Id.* With regard to NDEA, FDA testing showed that batches of Mylan API were all contaminated with NDEA greater than the FDA's ADI, ranging from slightly above ADI to over 14 times ADI. *Id.* And only one Aurobindo batch was recorded as below the level of quantification [redacted];[17] the other eight batches tested ranged from around three times ADI to up to more than 22 times ADI. *Id.* To the extent that there was variation among batches, the levels still exceeded the acceptable levels in nearly every tested batch. *Id.* Thus, there is common proof of significant exposure for the purposes of factual predominance.

E. The Class Action Device is Efficient

1. Superiority

Defendants contend that the Rule 23(b)(3) superiority requirement is not met. But Defendants fail to perform the correct analysis, rely upon the same distinguishable cases, and insert a misplaced Seventh Amendment argument that is not relevant to 23(b)(2). First, Defendants fail to acknowledge that the superiority analysis is inherently "comparative... with an eye toward 'other available methods.'" *Mullins v. Direct Digital, LLC,* 795 F.3d 654, 664 (7th Cir. 2015) (quoting Fed. R. Civ. P. 23(b)(3)). Defendants also fail to acknowledge the infinitely more complex and

2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products ("FDA Analysis").

[redacted]

resource-draining alternative—countless individual cases brought by consumers of VCDs that would still involve the same individual issues regarding exposure.[18] At bottom, Defendants' objection is really about the large number of class members impacted but this is no reason to immunize Defendants from classwide accountability. *Hardwick*, 2022 WL 668339, at *2 ("the size of the proposed class simply reflects the astonishing breadth of Defendants' misconduct").[19]

Additionally, Defendants' argument that Plaintiffs' proposed trial plan violates the Seventh Amendment is misplaced because if these classes are certified under Rule 23(b)(2), the Seventh Amendment is not implicated. *See Id.* at *11. Moreover, Plaintiffs' Exhibit G to their opening brief addresses Defendants' concern of overlap. Ex. 6, Pl's Cert. Br. at 4. Defendants fail to acknowledge that "[t]o avoid jury confusion the Court or a separate jury could hear evidence applicable only to the medical monitoring program." *Id.*[20] For prior reasons discussed, Defendant's citation to *Barnes* is likewise distinguishable.[21] *See supra* section II.D.2. Thus, there is no need to examine other risk factors.

2. The Implied Requirement of Ascertainability

At the outset, ascertainability is not a requirement for a Rule 23(b)(2) class seeking only injunctive and declaratory relief. *Shelton v. Bledsoe*, 775 F.3d 554, 563 (3d Cir. 2015). But even if the Court were to certify Plaintiffs' claims under Rule 23(b)(3), ascertainability would be easily

[18] The more realistic alternative is that the enormous cost and complexity of litigating these cases would preclude individual claims. *See e.g. Bentley v. Honeywell Int'l, Inc.*, 223 F.R.D. 471, 488 (S.D. Ohio 2004) (cases "which require sophisticated scientific inquiries and expensive experts to opine about them, cost thousands and sometimes millions of dollars to litigate.").

[19] Plaintiffs consent to dismiss Plaintiff Silberman without prejudice and, in so doing, address Defendants' concerns on the subject.

[20] Plaintiffs also reserved the right to amend the Trial Management Plan to address any concerns the Court may have. Ex. 6, Pl's Cert. Br. at 5.

[21] Defendants also cite to *Gates*, but the cited text merely parrots *Barnes* without adding any additional analysis. 655 F.3d at 268.

satisfied. An ascertainable class is "defined with reference to objective criteria," and there must be "a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 355 (3d Cir. 2013). The question of ascertainability "consists of nothing more than these two inquiries." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). Plaintiffs have satisfied both requirements. Both of the proposed Classes are defined by reference to the objective criteria of dosage, API manufacturer, and duration of consumption, based on relatively available records. *See* Ex. 6, Pl's Cert. Br. at 8-9; Ex. 4, Madigan Rpt. (Dkt. No. 1750-2) at 8-10 (delineating levels of Lifetime Cumulative Exposure to VCDs and the cancer risks associated with each exposure level).

Plaintiffs have also alleged a reliable and administratively feasible mechanism for determining class membership. Whether an individual is a member of a proposed Class is determinable by reference to Defendants' own data and, if necessary, data available from multiple sources. "Plaintiff need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc.*, 867 F.3d 434, 441-42 (3d Cir. 2017). Defendants are required by law to maintain information that is sufficient to create a "consumption record" for all potential class members. Ex. 6, Pl's Cert. Br. at 9; *see* Ex. 7, Craft Decl. at ¶¶ 15, 33-35. The Court can objectively identify class members via these records. *See* Ex. 6, Pl's Cert. Br. at 9-10; *see* Ex. 7, Craft Decl. at ¶ 12 ("Data already produced in this case confirm that Proposed Class Members can be identified.").

If necessary, the data could be supplemented with data from multiple redundant sources, including "Wholesalers, Retail Pharmacies, PBMs, and TPPs." Ex. 7, Craft Decl. at ¶¶ 9-10. Defendant objects that relevant data may not be readily available, *see* Ex. 1, Opp'n at 28, but this is no obstacle: "Post-discovery, post class-certification subpoenas are permissible to identify class

members and issue notice of the class action." *In re Suboxone Antitrust Litig.*, 421 F. Supp. 3d 12, 73 (E.D. Pa. 2019), *aff'd*, 967 F.3d 264 (3d Cir. 2020).[22] Filtering this data to determine whether an individual satisfies the three objective factors cited above provides the mechanism for identifying class members. *See Butela v. Midland Credit Mgmt.*, Civil Action No. 2:20-cv-1612, 2022 WL 1237047, at *15 (W.D. Pa. Apr. 27, 2022) ("Reviewing this information [to establish class membership] will, of course, require some level of individualized inquiry. But the need for file-by-file review to identify class members is not fatal to class certification." (internal citations and quotations omitted)); *Slamon v. Carrizo (Marcellus) LLC*, No. 3:16-CV-2187, WL 2525961, at *7 (M.D. Pa. May 18, 2020) (holding plaintiffs satisfied ascertainability when defendant possessed data necessary to establish class membership, even though it might be a difficult "manual process" for defendants). As "ascertainability only requires the plaintiff to show that class members can be identified," Plaintiffs have satisfied this requirement. *See Carrera v. Bayer Corp.*, 727 F.3d 300, 308 n.2 (3d Cir. 2013).[23]

At the merits stage, Plaintiffs will adduce common evidence establishing that all Class members have significantly increased risk of developing various cancers from consuming tainted VCDs.[24] Defendants assert that this Court should consider the question now by arguing that variations in contamination among the different lots of VCDs renders membership of the proposed Classes not ascertainable. Ex. 1, Opp'n at 28. In addition to being premature, this argument is

[redacted]

[23] To the extent there are any gaps in the records, Defendants "cannot avoid a class suit merely because their own actions have made the class more difficult to identify." *Practice Mgmt. Support Servs. v. Cirque Du Soleil, Inc.*, 301 F. Supp. 3d 840, 859 (N.D. Ill. 2018) (quoting *Appleton Elec. Co. v. Advance-United Expressways*, 494 F.2d 126, 135 (7th Cir. 1974)) (collecting authority).

[24] Specifically, esophageal, stomach, colorectal/intestinal, liver, lung, bladder, blood, pancreatic, and prostate cancer. *See* Ex. 4, Madigan Rpt. at 9-10.

irrelevant to the question of ascertainability and lacks factual support in Defendants' briefing.

Defendants' argument improperly "infuse[s] the ascertainability inquiry with other class-certification requirements." *Byrd*, 784 F.3d at 164-165 ("The predominance and ascertainability inquiries are distinct."). Defendants claim that "Plaintiffs must specify a defined level of exposure where there exists a significant risk of developing a disease" for the Classes to be ascertainable, Ex. 1, Opp'n at 28, and cite a case that was decided on predominance, not ascertainability. *See Gates.*, 655 F.3d at 274 (affirming the district court's denial of class certification due to the predominance of individual issues). Moreover, plaintiffs in that case failed to allege common evidence that would prove exposure to the toxin among all class members. *See id.* at 266 ("Plaintiffs cannot substitute evidence of exposure of actual class members with evidence of hypothetical, composite persons in order to gain class certification."). In contrast, here we have common evidence of actual exposure to NDMA and/or NDEA sufficient to cause a material increase in their cancer risks. *See* Ex. 4, Madigan Rpt. at 9-10; Ex. 3, Panigrahy Decl. at 222.

Next, Defendants' claims about variation in contamination among the different lots of VCDs is off point, and common evidence shows that all tested lots were materially contaminated. *See supra* section II.D.4. For the reasons articulated above, Plaintiffs have proven ascertainability. *Marcus v. BMW of N. Am. LLC*, 687 F.3d 583, 591-93 (3d Cir. 2012) (stating that plaintiffs must prove ascertainability "by a preponderance of the evidence"). [redacted]

3. Certification Under Rule 23(c)(4) is Available as Well

Alternatively, "[w]hen appropriate" this Court may still certify this class with "respect to particular issues" under Rule 23(c)(4). "An issues-class approach contemplates a bifurcated trial

where the common issues are tried first, followed by individual trials on questions such as proximate causation and damages." Role of Issues Classes, Ann. Manual Complex Lit. § 21.24 (4th ed.). Under the prevailing "broad view" of the rule adopted by the Third Circuit, "[a] majority of the courts of appeals have concluded that in appropriate cases Rule 23(c)(4) can be used even though full Rule 23(b)(3) certification is not possible due to the predominance infirmities." *Russell v. Educ. Comm'n for Foreign Med. Graduates*, 15 F.4th 259, 273 (3d Cir. 2021) (collecting cases). In this circuit, "district courts may certify 'particular issues' for class treatment [under Rule 23(c)(4)] even if those issues, once resolved, do not resolve a defendant's liability, provided that such certification substantially facilitates the resolution of the civil dispute, preserves the parties' procedural and substantive rights and responsibilities, and respects the constitutional and statutory rights of all class member and defendants." *Id.* at 269-70 ("courts commonly use Rule 23(c)(4) to certify some elements of liability for class determination, while leaving other elements to individual adjudication—or, perhaps more realistically, settlement") (quotations omitted).

In this case, certification of even part of the class would "materially advance the resolution of multiple civil claims by addressing the core of the dispute in a manner superior to other realistic procedural alternatives, so as to generate significant judicial efficiencies." Am Law Inst., Principles of the Law of Aggregate Litigation § 2.02 (2010). Here, issue classes could address the elements of exposure to a hazardous substance, whether Defendants' conduct here was wrongful, whether the amount of NDMA and NDEA at issue puts the class at an increased risk of cancer, and aspects of a monitoring program. Or, there can be issues limited to certain manufacturers.

III. CONCLUSION

Plaintiffs respectfully request that the Court grant their motion for class certification, appoint them as Class Representatives, and appoint Class Counsel.

Dated: May 10, 2022

Respectfully submitted,

By: */s/ Nicholas Migliaccio*
Nicholas Migliaccio
nmigliaccio@classlawdc.com
Jason Rathod
jrathod@classlawdc.com
MIGLIACCIO & RATHOD LLP
412 H Street NE, Suite 302
Washington, DC 20002
Telephone: (202) 470-3520
Facsimile: (202) 800-2730

Proposed Medical Monitoring Co-Lead Class Counsel

By: */s/ Rachel Geman*
Rachel Geman
rgeman@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, NY 10013-1413
Telephone: (212) 355-9500
Facsimile: (212) 355-9592

Proposed Medical Monitoring Co-Lead Class Counsel

By: */s/ Daniel Nigh*
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

By: */s/ Adam Slater*
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

By: */s/ Ruben Honik*
Ruben Honik
HONIK LLC
1515 Market Street, Ste. 1100
Philadelphia, PA 19102
Phone (267) 435-1300
ruben@honiklaw.com

By: */s/ Conlee S. Whiteley*
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel, on behalf of the Plaintiffs' Executive Committee and all Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of May, 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ Rachel Geman